

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEMS PRODUCTS LIABILITY
LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

ETHICON NON-REVISION PTO 298
(ELECTION WAVE) CASES LISTED IN
EXHIBIT A OF DEFENSE MOTION TO
EXCLUDE

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

**PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO
EXCLUDE THE GENERAL CAUSATION EXPERT OPINIONS OF
KONSTANTIN WALMSLEY, M.D. FOR NON-REVISION PTO 298 ELECTION WAVE**

Plaintiffs in the above-styled causes ("Plaintiffs") hereby adopt and incorporate by reference the responses to Daubert motions filed against Konstanin Walmsley, M.D. in Waves 1 (Dkt. No. 2171), 3 (Dkt. Nos. 2941, 2953), 4 (Dkt. No. 3783) and 8 (Dkt. No. 6962), and submit the following combined response and memorandum of law in opposition to Defendants' Motion to Exclude the General Causation Expert Opinions of Konstantin Walmsley, M.D. for Non-Revision PTO 298 Election Wave.

RESPONSE AND MEMORANDUM OF LAW

Dr. Walmsley presents two general opinions in his case-specific reports: (1) the risks associated with the TVT-O device at issue were not sufficiently addressed in that device's Instructions for Use ("IFU") at the time the plaintiff was implanted; and (2) there were safer alternative procedures available to treat stress urinary incontinence in women, including biologic slings and autologous fascial slings. *See* Def. Ex. B, Walmsley Harris Rpt. at 4-6; Def. Ex. C, Walmsley Ray Rpt. at 4-6.

Dr. Walmsley's General Opinion No. 1 and General Opinion No. 2 are both reliable, relevant to this litigation, and within his expertise. Therefore, both opinions should be admitted, and Defendants' motion should be denied.

1. Dr. Walmsley's Opinions on the IFU Are Reliable, Within His Expertise, and Admissible.

This Court has repeatedly held that an expert urogynecologist or urologist may testify as to the perceived risks associated with a mesh device and whether the IFU at issue conveyed those risks. *See, e.g., Wise v. C. R. Bard, Inc.*, No. 2:12-cv-01378, 2015 U.S. Dist. LEXIS 14869, at *15-16 (S.D. W. Va. Feb. 7, 2015) ("Dr. Ostergard will testify about the risks he perceives that the Avaulta poses to patients, and he will opine that the Avaulta IFU did not convey these risks. A urogynecologist like Dr. Ostergard is qualified to make this comparison."); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D. W. Va. 2014) ("Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU."); *see also, e.g., In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 U.S. Dist. LEXIS 145522, at *36 (S.D. Ill. Dec. 16, 2011) (denying defendant's motion to exclude testimony and ruling that "[d]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings").

Here, Dr. Walmsley is a practicing urologist who regularly treats women with stress urinary incontinence, implants mid-urethral slings, and treats women with mesh complications. *See, e.g., Def. Ex. B, Walmsley Harris Rpt.* at 1-2. As a practicing urologist who has used mesh and non-mesh slings to treat stress urinary incontinence, Dr. Walmsley is amply qualified to testify about the risks that are associated with the devices at issue and whether the product IFUs warned about those risks during the relevant timeframe. Dr. Walmsley is not being produced to

testify as to whether or not warning labels should be required, by law, to include these risks. Defendants' attempt to exclude Dr. Walmsley's relevant and reliable expert testimony by expanding its scope beyond its intended boundaries is misplaced. Dr. Walmsley does not seek to opine on what information should have been included by law in the IFU, but merely to compare the known risks of the devices and the warnings provided in their IFUs. Thus, Ethicon's motion should be denied.

In short, because Dr. Walmsley is qualified to compare the risks of the devices and the risks that were communicated in their IFUs, and because this information is relevant and will be helpful to the jury, Dr. Walmsley's opinions in this regard are admissible, and Defendants' motion should be denied.

2. Dr. Walmsley's Opinion on Safer Alternative Procedures Is Relevant and Admissible.

As a practicing urologist who has implanted both mesh and non-mesh slings, Dr. Walmsley is amply qualified to educate the jury on safer alternative procedures that were available to the plaintiffs, including biologic slings and autologous fascial slings. *See* Def. Ex. B, Walmsley Harris Rpt. at 6; Def. Ex. C, Walmsley Ray Rpt. at 6.

Indeed, Defendants do not challenge Dr. Walmsley's qualifications to offer such an opinion, but argue that a safer alternative procedure such as the autologous fascial sling is irrelevant to a design defect claim. *See* Def. Mem. at 4-6. Defendants' claim that the Plaintiffs should be forbidden to discuss any safer alternative procedures to treat stress urinary incontinence in women fails to consider the various issues to which such evidence is relevant. Evidence of safer alternative procedures compared to Ethicon's TVT-O products bears upon: (1) the risk-benefit analysis; (2) Ethicon's reasonableness in putting these devices on the market; and (3) punitive damages. Indeed, this Court should allow evidence related to other effective, safer

alternative procedures, as they are crucial to the implanting doctors' decisions of whether to use the TVT-O product, since available alternative procedures affect the risk-benefit analysis. Moreover, information on whether Defendants' mesh devices were actually an improvement over other procedures is important for the jury to determine the reasonableness of Ethicon's behavior in continuing to market the products despite known complications.

Accordingly, the Court should deny Defendants' motion as to Dr. Walmsley's opinion on safer alternative procedures such as the autologous fascial sling. Or, at the very least, the Court should reserve ruling on this opinion as the Court has done before, in order to allow the trial court to assess the relevance of this expert testimony firsthand and in the context of the particular state's law concerning negligence and products liability. *See, e.g., In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500765, at *3 (S.D. W. Va. Aug. 26, 2016) (reserving ruling until trial on the relevancy of safer alternative procedures, as the determination of relevance is "better decided on a case by case basis").

CONCLUSION

Dr. Walmsley's general opinions are reliable, relevant, and satisfy the requirements of *Daubert*. Defendants' motion to exclude Dr. Walmsley's general opinions should be denied.

Dated: December 28, 2018

Respectfully submitted,

/s/ D. Renee Baggett

Renee Baggett, Esq.

Bryan F. Aylstock, Esq.

Aylstock, Witkin, Kreis and Overholtz, PLC

17 East Main Street, Suite 200

Pensacola, Florida 32563

(850) 202-1010

(850) 916-7449 (fax)

E-mail: rbaggett@awkolaw.com

/s/ Thomas P. Cartmell

THOMAS P. CARTMELL

Wagstaff & Cartmell LLP

4740 Grand Avenue, Suite 300

Kansas City, MO 64112

816-701-1100

Fax 816-531-2372

tcartmell@wcllp.com

CERTIFICATE OF SERVICE

I hereby certify that on December 28, 2018, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Thomas P. Cartmell

THOMAS P. CARTMELL

Wagstaff & Cartmell LLP

4740 Grand Avenue, Suite 300

Kansas City, MO 64112

816-701-1100

Fax 816-531-2372

tcartmell@wcllp.com